

James A. Bonini, et al.
Serial No.: 09/609,146
Filed: June 30, 2000
Page 10

C8 which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.BS-rSNORF72-f (ATCC Patent Deposit Designation No. PTA-1927) or (2) the amino acid sequence shown in SEQ ID NO: 25.--

A marked-up version of the amendments showing the changes made is attached hereto as **Exhibit A**.

REMARKS

Claims 235-281 were pending in the subject application. By this Amendment, applicants have canceled claims 252, 253, 264, 265, and 272-275 without prejudice or disclaimer; and amended claims 235-237, 243-245, 249-251, 254, 258-259, 266-268, and 276-281. Accordingly, upon entry of this Amendment, claims 235-251, 254-263, 266-271, and 276-281 will be pending and under examination.

Applicants maintain that the amendments to claims 235-237, 243-245, 249-251, 254, 258-259, 266-268, and 276-281 raise no issue of new matter and is fully supported by the specification as filed.

Support for amended claims 235, 243, 249, 254, and 266 may be found inter alia in the specification, as originally-filed, on page 40, lines 11-24; and page 109, lines 17-25.

Support for amended claims 236, 244, 250, 258, 267, 277, and 280 may be found inter alia in the specification, as originally-filed, on page 42, line 32 through page 43, line 2; and page 29, lines 10-16.

Support for amended claims 237, 245, 251, 259, 268, 278, and 281

James A. Bonini, et al.
Serial No.:09/609,146
Filed: June 30, 2000
Page 11

may be found inter alia in the specification, as originally-filed, on page 43, lines 3-8; and page 29, lines 18-24.

Support for amended claims 276 and 279 may be found inter alia in the specification, as originally-filed, on page 74, lines 8-14; page 74, lines 21-23; page 101, lines 16-19; and page 57, lines 21-22.

Accordingly, applicants respectfully request that this Amendment be entered.

1. Restriction Requirement

On page 2 of the May 28, 2002 Office Action, the Examiner acknowledged applicants' election with traverse of Group I in Paper No. 12. The Examiner alleged that under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (M.P.E.P. §806.04-§806.04(I)) or distinct (MPEP §806.05- §806.05(I)). (Emphasis in original.) The Examiner further alleged that where inventions are related as disclosed but are distinct as claimed, restriction may be proper (M.P.E.P. §806(B)).

The Examiner alleged that consistent with current practice, a serious burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:. The Examiner then alleged that these criteria are met in the current restriction. The Examiner further alleged that the three groups require divergent searches, and to search all three inventions would be burdensome. The Examiner concluded that the restriction is maintained and therefore made final.

James A. Bonini, et al.
Serial No.:09/609,146
Filed: June 30, 2000
Page 12

In response to the Examiner's restriction, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have canceled claims 252, 253, 264, 265, and 272-275 without prejudice or disclaimer.

2. Information Disclosure Statement

On page 4 of the May 28, 2002 Office Action, the Examiner stated that the sequences disclosed in the IDS filed June 30, 2000 have not been considered. The Examiner alleged that without an explanation of relevance or a sequence alignment, the relevancy of the sequences cannot be determined.

Applicants have done the comparison of sequences previously cited in the IDS filed June 30, 2000. Accordingly, applicants hereby submit Table 1, attached hereto as **Exhibit B**. Table 1 lists each sequence accession number cited in the IDS, the sequence comparison to the human SNORF72 receptor (percent identity) for each sequence, and an explanation of relevance for each sequence.

Applicants respectfully request that the Examiner make the abovementioned sequences of record.

3. Priority

On page 4 of the May 28, 2002 Office Action, the Examiner alleged that the instant application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent applications 09/558,099 and 09/466,435. The Examiner suggested that a statement reading "(now abandoned)" should be included after the filing dates in the first sentence of the specification.

James A. Bonini, et al.
Serial No.:09/609,146
Filed: June 30, 2000
Page 13

In response, applicants have amended the specification to add the phrase "now abandoned" in reference to parent applications 09/558,099 and 09/466,435 in order to update the priority data of the subject application.

4. Rejections under 35 U.S.C. §112, first paragraph

4A. On page 4 of the May 28, 2002 Office Action, the Examiner rejected claims 235-251, 254-263, 266-271 and 276-281 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner alleged that the claims as written encompass using any mammalian SNORF72 receptor to screen for compounds that interact with the receptor. The Examiner stated that the instant disclosure of two polypeptide orthologs, that of SEQ ID NOS: 4 and 25, with the instantly disclosed activities, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. The Examiner alleged that a genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Examiner alleged that a description of a genus of SNORF72 receptors may be achieved by means of a recitation of a representative number of SNORF72 receptors, defined by polypeptide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus.

James A. Bonini, et al.
Serial No.:09/609,146
Filed: June 30, 2000
Page 14

In response, applicants maintain that the genus SNORF72 receptor is adequately described. For example, in the specification, as originally filed, on page 40, lines 11-24, the recitation "wherein the mammalian SNORF72 receptor has above 75% amino acid identity to the SNORF72 receptor encoded by (1) the nucleic acid sequence shown in SEQ ID NO:3 or (2) the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446)" reasonably conveys to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants further maintain that the amendments to claims 235-237, 243-245, 249-251, 254, 258-259, 266-268, 277-278, and 280-281 are fully supported by the specification as originally filed.

The Examiner further alleged that because the instant claims recite a functional limitation in the absence of any structural limitations, it is a single means claim which encompasses any protein which can function as a receptor to which any compound of unknown structure can bind. The Examiner concluded that the instant specification does not identify those defining structural elements which provide the functional and structural properties which is definitive of mammalian SNORF72 receptors.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claims 235-237, 243-245, 249-251, 254, 258-259, 266-268, 277-278, and 280-281 to define structural elements of mammalian SNORF72 receptors that are common to the genus.

Accordingly, applicants respectfully request that these rejections be reconsidered and withdrawn.

James A. Bonini, et al.
Serial No.: 09/609,146
Filed: June 30, 2000
Page 15

4B. On page 4 of the May 28, 2002 Office Action, the Examiner rejected claims 276-281 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner alleged that the specification has not described what a novel structural and functional analog or homolog of such a binding or antagonist compound would look like, and therefore does not meet the written description requirement.

In response, in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants have amended claims 276 and 279 to delete the phrase "or a novel structural and functional analog or homolog thereof".

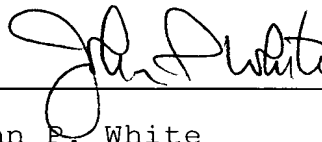
In summary, in light of the remarks made hereinabove, applicants respectfully request that the Examiner withdraw the various grounds of rejection set forth in the May 28, 2002 Office Action.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided.

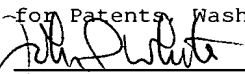
James A. Bonini, et al.
Serial No.:09/609,146
Filed: June 30, 2000
Page 16

No fee, other than the enclosed fee of \$200.00 for a two-month extension of time, is deemed necessary in connection with the filing of this Amendment and Petition For A Two-Month Extension Of Time. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
	10/28/02
John P. White Reg. No. 28,678	Date



1795/60794-B/JPW/PL

Marked-up Version of Amendments

Additions to the text are indicated by double underlining; deletions are indicated by square brackets.

In the Specification:

On page 1, line 7:

--This application is a continuation-in-part of U.S. Serial No. 09/558,099, filed April 25, 2000, now abandoned, which is a continuation-in-part of U.S. Serial No. 09/466,435, filed December 17, 1999, now abandoned, the contents of which are hereby incorporated by reference into the subject application.--

In the Claims:

--235. (Amended) A process involving competitive binding for identifying a chemical compound which specifically binds to a mammalian SNORF72 receptor which comprises separately contacting cells, or a membrane preparation from such cells, expressing on their cell surface the mammalian SNORF72 receptor, wherein such cells do not normally express the mammalian SNORF72 receptor, with both the chemical compound and a second chemical compound known to bind to the receptor, and with only the second chemical compound, under conditions suitable for binding of such compounds to the receptor, and detecting specific binding of the chemical compound to the mammalian SNORF72 receptor, a decrease in the binding of the second chemical compound to the mammalian SNORF72 receptor in the presence of the chemical compound being tested

indicating that such chemical compound binds to the mammalian SNORF72 receptor; wherein the mammalian SNORF72 receptor has above 75% amino acid identity to the SNORF72 receptor encoded by (1) the nucleic acid sequence shown in SEO ID NO:3 or (2) the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446).--

--236. (Amended) [The] A process of claim 235, wherein the mammalian SNORF72 receptor is a human SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446) or (2) the amino acid sequence shown in SEO ID NO: 4.--

--237. (Amended) [The] A process of claim 235, wherein the mammalian SNORF72 receptor is a rat SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.BS-rSNORF72-f (ATCC Patent Deposit Designation No. PTA-1927) or (2) the amino acid sequence shown in SEO ID NO: 25.--

--243. (Amended) A method of screening a plurality of chemical compounds not known to bind to a mammalian SNORF72 receptor to identify a compound which specifically binds to the mammalian SNORF72 receptor, which comprises

(a) contacting cells, or a membrane preparation from such cells, transfected with, and expressing, DNA encoding the mammalian SNORF72 receptor with a compound known to bind specifically to the mammalian SNORF72 receptor;

- (b) contacting the cells of step (a) with the plurality of compounds not known to bind specifically to the mammalian SNORF72 receptor, under conditions permitting binding of compounds known to bind to the mammalian SNORF72 receptor;
- (c) determining whether the binding of the compound known to bind to the mammalian SNORF72 receptor is reduced in the presence of the plurality of compounds, relative to the binding of the compound in the absence of the plurality of compounds; and if so
- (d) separately determining the binding to the mammalian SNORF72 receptor of each compound included in the plurality of compounds, so as to thereby identify any compound included therein which specifically binds to the mammalian SNORF72 receptor; wherein the mammalian SNORF72 receptor has above 75% amino acid identity to the SNORF72 receptor encoded by (1) the nucleic acid sequence shown in SEQ ID NO:3 or (2) the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446).--

--244. (Amended) [The] A method of claim 243, wherein the mammalian SNORF72 receptor is a human SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446) or (2) the amino acid sequence shown in SEQ ID NO: 4.--

--245. (Amended) [The] A method of claim 243, wherein the

mammalian SNORF72 receptor is a rat SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.BS-rSNORF72-f (ATCC Patent Deposit Designation No. PTA-1927) or (2) the amino acid sequence shown in SEQ ID NO: 25.--

--249. (Amended) A process for determining whether a chemical compound is a mammalian SNORF72 receptor antagonist which comprises contacting cells transfected with and expressing DNA encoding the mammalian SNORF72 receptor with the compound in the presence of a known mammalian SNORF72 receptor agonist, under conditions permitting the activation of the mammalian SNORF72 receptor, and detecting any decrease in mammalian SNORF72 receptor activity, so as to thereby determine whether the compound is a mammalian SNORF72 receptor antagonist; wherein the mammalian SNORF72 receptor has above 75% amino acid identity to the SNORF72 receptor encoded by (1) the nucleic acid sequence shown in SEQ ID NO:3 or (2) the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446).--

--250. (Amended) [The] A process of claim 249, wherein the mammalian SNORF72 receptor is a human SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446) or (2) the amino acid sequence shown in SEQ ID NO: 4.--

--251. (Amended) [The] A process of claim 249, wherein the mammalian SNORF72 receptor is a rat SNORF72 receptor which has an amino acid sequence identical to (1) that

encoded by the plasmid pEXJ.BS-rSNORF72-f (ATCC Patent Deposit Designation No. PTA-1927) or (2) the amino acid sequence shown in SEQ ID NO: 25.--

--254. (Amended) A process for determining whether a chemical compound specifically binds to and inhibits activation of a mammalian SNORF72 receptor, which comprises separately contacting cells producing a second messenger response and expressing on their cell surface the mammalian SNORF72 receptor, wherein such cells do not normally express the mammalian SNORF72 receptor, with both the chemical compound and a second chemical compound known to activate the mammalian SNORF72 receptor, and with only the second chemical compound, under conditions suitable for activation of the mammalian SNORF72 receptor, and measuring the second messenger response in the presence of only the second chemical compound and in the presence of both the second chemical compound and the chemical compound, a smaller change in the second messenger response in the presence of both the chemical compound and the second chemical compound than in the presence of only the second chemical compound indicating that the chemical compound inhibits activation of the mammalian SNORF72 receptor; wherein the mammalian SNORF72 receptor has above 75% amino acid identity to the SNORF72 receptor encoded by (1) the nucleic acid sequence shown in SEQ ID NO:3 or (2) the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446).--

--258. (Amended) A process of any of claims 254, 255, 256 or 257, wherein the mammalian SNORF72 receptor is a human SNORF72 receptor which has an amino acid sequence

identical to (1) that encoded by the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446) or (2) the amino acid sequence shown in SEQ ID NO: 4.--

--259. (Amended) A process of any of claims 254, 255, 256 or 257, wherein the mammalian SNORF72 receptor is a rat SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.BS-rSNORF72-f (ATCC Patent Deposit Designation No. PTA-1927) or (2) the amino acid sequence shown in SEQ ID NO: 25.--

--266. (Amended) A method of screening a plurality of chemical compounds not known to inhibit the activation of a mammalian SNORF72 receptor to identify a compound which inhibits the activation of the mammalian SNORF72 receptor, which comprises:

- (a) contacting cells transfected with and expressing the mammalian SNORF72 receptor with the plurality of compounds in the presence of a known mammalian SNORF72 receptor agonist, under conditions permitting activation of the mammalian SNORF72 receptor;
- (b) determining whether the extent or amount of activation of the mammalian SNORF72 receptor is reduced in the presence of one or more of the compounds, relative to the extent or amount of activation of the mammalian SNORF72 receptor in the absence of such one or more compounds; and if so
- (c) separately determining whether each such compound

inhibits activation of the mammalian SNORF72 receptor for each compound included in the plurality of compounds, so as to thereby identify any compound included in such plurality of compounds which inhibits the activation of the mammalian SNORF72 receptor; wherein the mammalian SNORF72 receptor has above 75% amino acid identity to the SNORF72 receptor encoded by (1) the nucleic acid sequence shown in SEO ID NO:3 or (2) the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446).--

- 267. (Amended) [The] A method of claim 266, wherein the mammalian SNORF72 receptor is a human SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446) or (2) the amino acid sequence shown in SEO ID NO: 4.--
- 268. (Amended) [The] A method of claim 266, wherein the mammalian SNORF72 receptor is a rat SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.BS-rSNORF72-f (ATCC Patent Deposit Designation No. PTA-1927) or (2) the amino acid sequence shown in SEO ID NO: 25.--
- 276. (Amended) A process for preparing a composition which comprises a chemical compound identified by the process of any of claims 235 or 243, [or a novel structural and functional analog or homolog thereof,] recovering the compound free of any receptor, and admixing with a pharmaceutically acceptable carrier.--

- 277. (Amended) The process of claim 276, wherein the mammalian SNORF72 receptor is a human SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446) or (2) the amino acid sequence shown in SEQ ID NO: 4.--
- 278. (Amended) The process of claim 276, wherein the mammalian SNORF72 receptor is a rat SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.BS-rSNORF72-f (ATCC Patent Deposit Designation No. PTA-1927) or (2) the amino acid sequence shown in SEQ ID NO: 25.--
- 279. (Amended) A process for preparing a composition which comprises a chemical compound identified by the process of any of claims 249, 254 or 266, [or a novel structural and functional analog or homolog thereof,] recovering the compound free of any receptor, and admixing with a pharmaceutically acceptable carrier.--
- 280. (Amended) The process of claim 279, wherein the mammalian SNORF72 receptor is a human SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.T3T7-hSNORF72-f (ATCC Patent Deposit Designation No. PTA-1446) or (2) the amino acid sequence shown in SEQ ID NO: 4.--
- 281. (Amended) The process of claim 279, wherein the mammalian SNORF72 receptor is a rat SNORF72 receptor which has an amino acid sequence identical to (1) that encoded by the plasmid pEXJ.BS-rSNORF72-f (ATCC Patent Deposit

1795/60794-B/JPW/PL

Designation No. PTA-1927) or (2) the amino acid sequence
shown in SEO ID NO: 25.--